Food and Drug Administration, HHS

§522.840 Estradiol.

- (a) Specifications. Each silicone rubber implant contains 25.7 or 43.9 milligrams of estradiol.
- (b) Sponsor. See 000986 in 510.600(c) of this chapter.
- (c) Conditions of use. It is used for implantation in steers and heifers as follows:
- (1) *Amount*. Insert one 25.7-milligram implant every 200 days; insert one 43.9-milligram implant every 400 days.
- (2) Indications for use. For increased rate of weight gain in suckling and pastured growing steers; for improved feed efficiency and increased rate of weight gain in confined steers and heifers.
- (3) Limitations. For subcutaneous ear implantation in steers and heifers only. A second implant may be used if desired. No additional effectiveness may be expected from reimplanting in less than 200 days for the 25.7-milligram implant or 400 days for the 43.9 milligram implant. Increased sexual activity (bulling, riding, and excitability) has been reported in implanted animals.

[51 FR 22276, June 19, 1986, as amended at 57 FR 41861, Sept. 14, 1992]

§ 522.842 Estradiol benzoate and testosterone propionate in combination

- (a) [Reserved]
- (b) Sponsors. See 000856 in §510.600(c) of this chapter for use as in paragraph (d)(1)(i), (d)(2), and (d)(3) of this section. See 021641 in §510.600(c) of this chapter for use as in paragraph (d) of this section.
- (c) Related tolerances. See §§ 556.240 and 556.710 of this chapter.
- (d) Conditions of use—Heifers. For implantation as follows:
- (1) Amount. (i) 20 milligrams of estradiol benzoate and 200 milligrams of testosterone propionate per dose.
- (ii) 20 milligrams estradiol benzoate and 200 milligrams testosterone propionate in eight pellets with 29 milligrams tylosin tartrate as a local antibacterial in one pellet, per implant dose.
- (2) Indications for use. Growth promotion and improved feed efficiency.
- (3) *Limitations*. For heifers weighing 400 pounds or more; for subcutaneous ear implantation, one dose per animal;

not for use in dairy or beef replacement heifers.

[40 FR 13858, Mar. 27, 1975, as amended at 49 FR 29778, July 24, 1984; 61 FR 5506, Feb. 13, 1996; 64 FR 48294, Sept. 3, 1999]

§ 522.850 Estradiol valerate and norgestomet in combination.

- (a) *Specifications*. The product is a two-component drug consisting of the following:
- (1) An implant containing 6.0 milligrams of norgestomet.
- (2) An injectable solution (sesame oil) containing 3.0 milligrams of norgestomet and 5.0 milligrams of estradiol valerate per 2 milliliters.
- (b) Sponsor. See 050604 in \$510.600(c) of this chapter.
- (c) Conditions of use—(1) Amount. One implant and 2 milliliters of injection at time of implantation.
- (2) Indications for use. For synchronization of estrus/ovulation in cycling beef cattle and non-lactating dairy heifers.
- (3) Limitations.Insert implant subcutaneously in the ear only; then immediately inject solution intramuscularly only. Counting the day of implantation as day 1, remove the implant on day 10. Collect all implants as they are removed and burn them. While animals are restrained for artificial insemination, avoid other treatments such as vaccinations, dipping, pour-on grub and louse prevention, spraying, etc. When inseminating without estrus detection, the entire treated group should be started at 48 hours after the last implant has been removed and should be completed within 6 hours. Where estrus detection is preferred, insemination should be approximately 12 hours after first detection of estrus. Those that do not conceive can be re-bred when they return to estrus approximately 17 to 25 days after implant removal. Do not use in cows producing milk for human consumption.

[47 FR 55477, Dec. 10, 1982, as amended at 48 FR 49656, Oct. 27, 1983; 51 FR 33592, Sept. 22, 1986; 54 FR 1165, Jan. 12, 1989]